will convey tasks to TARGET Data Systems, Inc., and will itself perform tasks to develop, maintain, and operate software to assist in the collection, storage, processing and analysis of confidential TSCA data at the secure computer data center at EPA's regional office in Research Triangle Park, North Carolina. AMS and TARGET will require access to information submitted under section 8 (a) and (d) of TSCA.

In accordance with 40 CFR 2.306(j), it has been determined that access to TSCA confidential business information by AMS and TARGET will be necessary for the satisfactory performance of work under this contract.

AMS and TARGET are legally required under the terms of their respective contracts to safeguard from any unauthorized disclosure the confidential business information to which they receive access from EPA or which they generate during the performance of their work. Neither AMS nor TARGET will remove any confidential business information from EPA premises.

AMS and TARGET personnel will be required to sign a nondisclosure agreement before they are permitted access to confidential information. AMS and TARGET are required to treat all confidential business information in accordance with the requirements of the "TSCA Confidential Business Information Security Manual" and the "Contractor Requirements for the Control and Security of TSCA Confidential Business Information Manual."

Dated: October 26, 1982.

Don R. Clay,

Director, Office of Toxic Substances.

[FR Doc. 82-30624 Filed 11-5-82; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-140024; TSH-FRL-2240-8]

Tracor Jitco, Inc.; Transfer of Data to Contractor

AGENCY: Environmental Protection Agency (EPA). **ACTION:** Notice.

SUMMARY: EPA will transfer to its contractor, Tracor Jitco, Inc., of Rockville, Maryland, information which has been or will be submitted by manufacturers and importers under section 5 of the Toxic Substances Control Act (TSCA). Some of the information may be claimed confidential. Tracor Jitco, Inc., will review this information and use it to perform literature searches on the health and environmental effects of the

chemical substances or analogs and submit the results to EPA.

DATE: The transfer of data submitted to EPA and claimed to be confidential will occur no sooner than 10 working days after publication of this notice in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-511, 401 M St. SW., Washington, D.C. 20460, Toll-free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION: Under section 5 of TSCA, 15 U.S.C. 2604, EPA must determine whether or not certain chemical substances or mixtures may present an unreasonable risk of injury to health or the environment from their manufacture, processing, distribution in commerce, use, or disposal. As a component of the unreasonable risk determination, the Agency must ascertain whether or not there is potential for a health and/or environmental hazard or risk from exposure to the substances or mixtures in question. To accomplish this, EPA will require the assistance of outside experts. Tracor Jitco, Inc., of Rockville. Maryland, is assisting EPA in conducting literature searches to locate studies which have been done on these chemical substances or mixtures (Contract No. 68-01-6651). In particular, the contractor will be searching the literature for material on health and environmental effects of PMN substances and their analogs.

Under 40 CFR 2.306(j), EPA has determined that it will need to disclose confidential business information to Tracor Jitco, Inc. Under the terms of the contract, EPA will provide the contractor with information submitted in premanufacturing notices (PMN's), including chemical identity. manufacturer identity, product formulation, and specific processes used to manufacture or process new chemical substances, as well as other information related to the uses, release rates, exposure levels, and assessment of potential hazard and/or risk to health and the environment of new chemical substances.

Under the EPA Contractor
Requirements for the Control and
Security of TSCA Confidential Business
Information Manual, Tracor Jitco, Inc.,
has been authorized to have access to
this information. EPA has approved the
contractor's security plan and has
conducted the required inspection of its
facilities and found them to be in

compliance with the provisions of the manual.

EPA is publishing this notice to inform all submitters of PMN's that Tracor Jitco, Inc., will receive confidential business information in PMN's from EPA. After completing the literature searches, Tracor Jitco, Inc., will return all confidential business information to EPA.

The Tracor Jitco, Inc., personnel will be required to sign a nondisclosure agreement before they are permitted access to confidential business information. Tracor Jitco, Inc., is required to treat all such information in accordance with the requirements of the TSCA Confidential Business Information Security Manual and the Contractor Requirements for the Control and Security of TSCA Confidential Business Information Manual.

Dated: October 26, 1982.

Don R. Clay,

Director, Office of Toxic Substances.

[FR Doc. 82-30620 Filed 11-5-82; 8:45 am]

BILLING CODE 5560-01-M

[OPTS-42026; THS-FRL-2224-2]

Toxic Substances; 4-Chlorobenzotrifluoride; Response to Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and Request for Comments.

SUMMARY: The Ninth Report of the Interagency Testing Committee (ITC) designated the chemical 4chlorobenzotrifluoride (4-CBTF) for health and environmental effects testing consideration. Following the designation, Occidental Chemical Corporation, the sole American manufacturer of 4-CBTF, presented to the EPA plans for testing the health and environmental effects of 4-CBTF. The Agency has tentatively concluded that the program appears acceptable in lieu of a test rule. Consequently, at this time, the EPA is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require health or environmental effects testing of 4-CBTF. This notice constitutes the Agency's response to the ITC's designation of 4-CBTF, as mandated by section 4(e) of TSCA. Interested persons are invited to comment on this tentative decision.

DATE: All comments should be submitted on or before January 7, 1983.

ADDRESS: Written comments should bear the document control number

OPTS-42026 and should be submitted to:
Document Control Officer (TS-793),
Office of Pesticides and Toxic
Substances, Environmental Protection
Agency, Room E-409, 401 M Street, SW,
Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:
Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799),
Office of Toxic Substances,
Environmental Protection Agency, Room E-511, Washington, D.C. 20460. Toll
Free: (800-424-9065). In Washington,
D.C.: (554-1404). Outside the USA:
(Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) authorizes EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations at any one time for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or publishing in the Federal Register reasons for not doing so.

The ITC placed 4-ČBTF on its priority testing list published in the Federal Register of October 30, 1981 (47 FR 5456) and designated it for testing for chronic effects, chemical fate, and bioconcentration. The reasons for the ITC's recommendations were (1) the high production volume of 4-CBTF, (2) positive results in two short term assays (sister chromatid exchange and unscheduled DNA synthesis), (3) the detection of 4-CBTF in the edible portion of 3 species of freshwater fish in the Niagara River, and (4) the lack of data on environmental fate and transport.

II. Health and Environmental Effects

4-CBTF is a clear, colorless liquid at room temperature with a naphthalene-like odor. Hooker Chemicals and Plastics Corporation (now Occidental Chemical Corporation) in Niagara Falls, New York, reported a 1977 production volume of 10-50 million pounds in the TSCA Inventory (Ref. 28). Occidental is the only major producer of 4-CBTF in the United States. The major use of 4-CBTF is as an intermediate in the manufacture of dinitroaniline herbicides

such as trifluralin (Ref. 11). The main route of environmental entry of 4-CBTF is leaching and runoff from disposal sites. Hooker disposed of 8,500 tons of benzotrifluoride and benzotrifluoride derivatives in the Hyde Park Landfill in Niagara Falls between 1953 and 1975 (Ref. 12). Low levels of 4-CBTF have been detected in Bloody Run Creek, which is a drainage ditch leading from the landfill to the Niagara River, and in fish in the river (Refs. 7 and 30). Occidental is no longer disposing of waste in the landfill and, has provided confidential information showing that environmental releases from the manufacture of 4-CBTF have been reduced considerably (Ref. 8).

The Agency found no specific information on the transport and fate of 4-CBTF in the environment. 4-CBTF has low water solubility (29.1 ± 4.8 ppm at 23°C) and a relatively high vapor pressure of 5.8 mm Hg at 20°C and would be expected to evaporate from surfaces into the atmosphere (Refs. 9 and 10). The evaporation half-life of 4-CBTF from water can be estimated to be about 7.06 hours at a depth of 1 meter (Refs. 4 and 20). Adsorption to organic sediments may be a competing process in the environment. The soil adsorption coefficient of 4-CBTF, calculated from its water solubility, indicates that 4-CBTF would be expected to adsorb to organic matter in soils and sediments (Refs. 3 and 13). The Agency has no information on the biodegradability of 4-CBTF or on chemical transformation processes relevant to determining the persistence of this compound in the environment.

The ITC was concerned about the potential of 4-CBTF to bioconcentrate. Calculated bioconcentration factors ranging from 92 to 396 indicate that 4-CBTF has a low to moderate potential to bioconcentrate (Refs. 14, 21, and 29). These estimates have not been experimentally verified for 4-CBTF. The compound has been detected at levels of 0.17 to 2.0 ppm in the edible portion of fish taken from the Niagara River (Ref. 30).

4-CBTF has been characterized as being moderately toxic to aquatic organisms on an acute exposure basis (Refs. 25 and 26). The potential chronic effects of 4-CBTF to aquatic organisms have been characterized in a 21-day chronic study with Daphnia (LC50, 0.05 mg/1) and in an early life-stage test. The maximum acceptable toxicant concentration (MATC) for fathead minnows and larvae was estimated to be greater than 0.54 mg/l and less than 1.4 mg/l. (Refs. 5 and 27).

4-CBTF shows low acute toxicity when given orally to rats $(LD_{50} > 6.7g/kg)$

or applied dermally to rabbits $(LD_{50}>2.7\mathrm{g/kg})$ [Refs. 23 and 24]. The acute inhalation toxicity (LD_{50}) in rats was reported to be 33 mg/1 for a 4-hour exposure [Ref. 2]. A 90-day subchronic oral toxicity study in rats was modified according to an FDA protocol used to evaluate the safety of low level exposure to contaminants (Ref. 6). The no-effect level was judged to be 45 mg/kg/day or greater since no toxic effects were observed in the study.

The mutagenicity of 4-CBTF has been investigated in bacterial, yeast and cell culture systems. The results were negative in the microbial mutagenesis systems tested (Salmonella, E. Coli and Saccharomyces) (Ref. 15). No evidence of mutagenic material was found in mouse urine in an in vivo/in vitro urine assay (Ref. 18). However, this conclusion may not be accurate because of questions about the experimental design. Statistically significant increases were observed in the sister chromatid exchange assay using L-5178Y cells when tested both with and without activation (Ref. 17). In cell culture systems, 4-CBTF gave negative results in both the forward mutation assay with mouse lymphoma cells (L5178Y) and the in vitro transformation assay using BALB/3T3 cells [Refs. 16 and 19). The latter study was conducted without metabloic activation making the results inconclusive. 4-CBTF was reported to induce unscheduled DNA synthesis in EUE cells; however, no details of the study were provided [Ref. 1].

III. Proposed Testing

Occidental Chemical Corporation presented a detailed testing proposal for 4-CBTF to the EPA in August, 1982 (Ref. 22). The Occidental proposal consists of tiered systems for testing both health and environmental effects, with lower tier tests acting as triggers to additional testing or as stop points following review of the data with EPA personnel. The health effects testing program is divided into four major testing segments: (1) Acute toxicity screen which has already been completed, (2) base set of tests, (3) conditional tests, and (4) additional mammalian testing, with three full program reviews (December 1983, March 1984, and March 1985). The environmental effects testing is divided into: (1) Screening tests (acute toxicity, physical/chemical properties), (2) base set of tests, and (3) conditional tests, with one full program review occurring in November 1983.

The Occidental testing program will develop base sets of data for both environmental and health effects. For environmental effects, the base set data

are derived from complete and partial life cycle tests using Daphnia and fathead minnow respectively, bluegill flowthrough bioaccumulation tests, soil adsoprtion/desorption tests, volatilization from water and photolysis in water studies, and anaerobic and aerobic aquatic metabolism investigations. The complete and partial life cycle tests are already completed; the other studies are scheduled to be completed in August 1983. For health effects, the base set data are derived from subchronic exposure studies, primary metabolic studies (already completed), and mutagenicity and cell transformation studies (to be completed in August, 1983). Occidental is proposing to conduct a new 90-day subchronic toxicity study (scheduled for completion by November, 1983) because the existing study did not include a dose level at which toxic effects were observed. After a review of results from the base set tests by Occidental and EPA personnel, a determination will be made if further studies are necessary, such as metabolic, reproductive, teratogenci, and atmospheric fate studies. Depending on the outcome of the base set tests, other testing such as carcinogenicity or effects on benthic organisms also may need to be considered.

Occidental will supply EPA with the name and address of the laboratory(ies) conducting the tests under this agreement. Occidental has agreed to adhere to the Good Laboratory Practice Standards issued by the U.S. Food and Drug Administration as published in the Federal Register of December 22, 1978 (43 FR 59986). All testing protocols will be reviewed and approved by EPA. Occidental also has agreed to permit laboratory audits/inspections in accordance with the procedures outlined in TSCA section 11 at the request of authorized representatives of the EPA for the purpose of determining compliance with this agreement. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to Good Laboratory Practices.

Occidental has further agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained as specified in the FDA Good Laboratory Practice Standards and made available during an inspection or submitted to EPA if requested by EPA or its authorized representative.

Occidental understands that the Agency plans to publish in the Federal Register a notice of the receipt of any test data submitted under this agreement. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Finally, Occidental understands that failure to conduct the testing according to the specified protocols and failure to follow Good Laboratory Practices may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule or otherwise require further testing.

IV. Decision Not To Require Testing

The proposed Occidental testing program addresses the ITC's recommendations concerning chronic effects, chemical fate and bioconcentration testing for 4-CBTF. The Agency, therefore, is proposing not to require testing under section 4 of TSCA.

For implementing TSCA section 4. EPA generally accepts subchronic toxicity testing as a surrogate for chronic toxicity testing, with the exception of oncogenicity, delayed toxicity and age-related endpoints. The ITC did not indicate concern for these, and EPA is aware of no data indicating that 4-CBTF may cause delayed or agerelated effects. Therefore, it is the Agency's view that the proposed 90-day subchronic toxicity study of 4-CBTF is likely to provide adequate data to reasonably predict its non-oncogenic chronic toxicity.

In EPA's view, the two mutagenicity tests reported to be positive for 4-CBTF (sister chromated exchange and unscheduled DNA synthesis) do not, in the light of the other negative mutagenicity test results, warrant initiation of a lifetime oncogenicity bioassay at this time. Neither did the ITC recommend oncogenicity testing. The additional mutagenicity and cell transformation tests to be performed by Occidental will provide a basis for deciding whether oncogenicity testing is needed.

Although the ITC did not specifically recommend further testing for mutagenicity, there is some basis for concern as to the mutagenic potential of 4—CBTF because of the positive results reported in two studies. Occidental has proposed doing a chromosomal aberrations testing battery which, along with the gene mutation testing already completed, comprises the mutagenicity testing that EPA normally requires as

the first tier of a section 4 test rule. If the results of the proposed tests indicate the need for additional testing, EPA may either come to an agreement with Occidental to do the additional testing or, if that proves unsatisfactory, EPA reserves the right to promulgate a test rule.

EPA also has concluded that the testing completed or committed to under the Occidental environmental testing program can be expected to yield data sufficient to reasonably predict the chemical fate and bioconcentration potential of 4-CBTF. The base set testing focuses on the aquatic environment, which is where 4-CBTF has been detected. Atmospheric fate testing will depend on the results of the base set tests and the development of suitable procedures for evaluating 4-CBTF's fate in the atmosphere. If the results of Occidental's testing or other data indicate the need for additional testing which Occidental does not agree to perform, EPA reserves the right to promulgate a test rule.

Because of the expectation that data received from the testing already undertaken and committed to by Occidental will permit EPA to reasonably determine or predict the effects of concern highlighted by ITC, and the fact that the testing will be conducted more expeditiously than would be possible under a test rule, EPA has tentatively concluded not to initiate rulemaking to require testing at this time. EPA's conclusion that the test data provided will serve to reasonably predict these effects is reinforced by the provision for inspections to verify that the testing is being properly conducted. In addition, the data developed by Occidental will be available to the public on a similar basis as the results of a test rule.

In order to provide the same type of opportunity for public input that would be served by public comment on a proposed test rule, EPA is soliciting comments on the Occidental program and the Agency decision to accept it in lieu of section 4(a) rulemaking. After considering these comments, EPA will either publish in the Federal Register a final notice of acceptance of a negotiated test program or will initiate rulemaking under section 4(a) of TSCA.

V. References

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VI. Public Record

The EPA has established a public record for this testing decision (docket number OPTS-42026). This record includes:

- (1) Federal Register notice designating 4-CBTF to the priority list.
- (2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.
 - (3) Testing proposals and protocols.
 - (4) Published and unpublished data.
- (5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday in Room E–107, 401 M Street, SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: October 29, 1982.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-30625 Filed 11-5-82; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL RESERVE SYSTEM

Agency Forms Under Review

November 1, 1982.

Background

When executive departments and independent agencies propose public use forms, reporting, or recordkeeping requirements, the Office of Management and Budget (OMB) reviews and acts on those requirements under the Paperwork Reduction Act (44 U.S.C. Chapter 35). Departments and agencies use a number of techniques to consult with the public on significant reporting requirements before seeking OMB approval. OMB in carrying out its responsibilities under the act also considers comments on the forms and recordkeeping requirements that will affect the public. Reporting or recordkeeping requirements that appear to raise no significant issues are approved promptly. OMB's usual practice is not to take any action on proposed reporting requirements until at least ten working days after notice in the Federal Register but occasionally the public interest requires more rapid action.